MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Representation in Research

Remarks for Rep. Robin Kelly's Roundtable to Diversify Clinical Trials

Good afternoon, and thank you for inviting us

My name is Hayat Ahmed, and I am a Program Manager at the Multi-Regional Clinical Trials Center at Brigham and Women's Hospital and Harvard. The MRCT center is a policy and research organization that convenes multiple parties including academia, industry, patients and patient advocacy groups, and regulatory agencies, to address critical issues in the conduct and oversight of clinical trials.

Over the past ten years, we have worked to improve diversity equity and inclusion in clinical research. The MRCT Center's Representation in Clinical Research program has released several important tools: the **Achieving Diversity, Inclusion, Equity in Clinical Research Guidance Document and Toolkit** (2020), the **IRB and HRPP DEI Toolkit** (2022), the **Accessibility by Design in Clinical Research Toolkit** (2023), and tools for **LGBTQIA+ populations** and **Global populations** (2024). While we have made significant progress, we recognize the continued need for learning and action to enhance health equity and justice in clinical research.

Our recent collaboration with the Clinical Trials Transformation Initiative and the Milken Institute culminated in a document entitled, "*Toward a National Action Plan for Achieving Diversity in Clinical Trials*." This work identifies eight critical domains for action, which I briefly outline.

First, **Public Awareness & Communication**: We need a national campaign that actively engages communities that have been historically underrepresented in clinical research. By identifying effective outreach strategies and messaging that resonates with different populations, we can build trust, dismantle misconceptions about clinical trials, and ensure individuals can make informed decisions about their participation.

Second, **Community Engagement & Investment**: Sustainable partnerships with and investment in community organizations are essential. We must empower communities to articulate their research needs and ensure transparent communication of research results, fostering an environment of trust and collaboration.

Third, Clinical Trial **Site Enablement**: We need to enhance the capacity of local research sites. This involves emphasizing strengths, revising funding models, and providing accessible training resources and mentorship to support local practitioners.

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Fourth, **Workforce Diversity**: A representative and diverse clinical research workforce is vital. We must promote awareness of clinical trial careers and ensure equitable access to educational opportunities, internships, and fellowships, while also focusing on fair wages and advancement opportunities.

Fifth, **Equitable Trial Participation Access**: To address participation barriers, we must partner with advocacy groups to create resources that help individuals navigate the clinical trial landscape. Plain language, accessible technology, and financial neutrality will help ensure that all potential participants feel informed and supported.

Sixth, **Funding, Resources, and Support**: We need to allocate funding specifically to activities that enhance diversity in clinical trials. This includes revising insurance policies to support trial participation and creating mechanisms for sustained community investment. *The Clinical Trial Modernization Act* and *the Clinical Trial Participant Income Exemption Act* are promising efforts.

Seventh, **Comprehensive Data**: Establishing a national system for the collection of demographic and non-demographic data is essential for accountability and improvement. By standardizing data practices, we can better identify and address barriers to participation.

Lastly, **Accountability**: We need a robust framework to ensure transparency in our health equity efforts. This includes developing performance measures and requiring diversity plans from the FDA before pivotal studies proceed.

As we move forward, here are three key legislative goals to consider:

1. **Establish national insurance coverage policies, for public and private payers, and tax-free payments that support clinical trial participation**, ensuring financial barriers do not prevent individuals from joining important studies.
2. **Provide resources to aid participants in finding trials and in navigating and affording participation**, making the process more accessible and less intimidating.
3. **Establish a national reporting framework to share progress on diversity metrics and progress to goals**, holding all stakeholders accountable for making tangible improvements.

By focusing on specific goals, we can make significant strides toward achieving health equity in clinical trials. Thank you for your attention!